IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez

Application No.: 10/696,258 Confirmation No.: 7051

Filed: October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR

ATLMENTS

Art Unit : 3769

Examiner : David M. Shay

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

## DECLARATION UNDER 37 C.f.R. § 1.132 OF SANDRA L. CURET

Sir:

- I, Sandra L. Curet, hereby declare as follows:
- That I graduated from the University of Puerto Rico, School of Medicine, located in San Juan, Puerto Rico with a Medical Doctor degree in 1988;
- 2. That I have been practicing as an Obstetric and Gynecologist physician for the past 17 years and am very familiar with the ailment of hemorrhoids. Moreover, I am currently a full-time faculty member in the Department of Obstetrics and Gynecology at Lehigh Valley Hospital located in Allentown, Pennsylvania. I am currently the Director of

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Ambulatory Services for the Center for Women's Health at Lehigh Valley Hospital located in Allentown, Pennsylvania.

- 3. That I am very familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I have reviewed the Application and the claims therein which are at issue:
- 4. That I am very familiar with the structural design and purpose of the claimed invention, and have been following the progress of the claimed invention throughout its development by the inventor, Rebecca Gomez. The claimed invention has an ergonomic structure that does not restrict a patient's movement and is comfortable to wear, thus allowing a patient to continue with their daily activities despite the presence of the hemorrhoid or the wearing of the claimed invention. The claimed invention can operate by separating the inflamed tissue, thus resulting in the quickened healing of the hemorrhoid and the reduction of the hemorrhoid's associated pain. Furthermore, the claimed invention is easily applied and is user-friendly for a patient;
- 5. That, in my expert opinion, the product is very effective in providing relief of hemorrhoidal pain and in healing hemorrhoids, and thus helps improve and maintain the quality of life in patients. I am eager for the claimed invention to become available on the market and fully intend to recommend the claimed invention for use by my patients when it does become available;

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- 6. That I am familiar with the following Rosenberg reference cited by the Examiner, The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal Wound (hereinafter referred to as "Rosenberg"). It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the Application have been rejected by the Examiner based on Rosenberg:
- 7. That I have reviewed the Rosenberg publication and have compared the technology described therein to the claimed invention of the Application. Rosenberg describes a "reverse bandaging" technique in which an adhesive strapping is strapped to a person's buttocks and crossed in front of the abdomen;
- 8. That both the description and the purpose of the technology in Rosenberg are different from the claimed invention. As one example, the technology of Rosenberg is designed to work in a different anatomical area than the claimed invention. As another example, the technology of Rosenberg is designed for treating a wound following a pilonidal cyst surgery, whereas the structure of the claimed invention can be used for reducing inflammation and pain associated with hemorrhoids and enhancing the healing of the hemorrhoid. The claimed invention can provide such a high degree of healing that it can even obviate the need for performing surgery on the hemorrhoid:
- 9. That the above-mentioned differences between Rosenberg and the claimed invention demonstrate the superiority of the claimed invention over Rosenberg;

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- 10. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been obvious to one skilled in art at the time the Application was filed:
- 11. That Rosenberg moreover does not show the claimed invention. Rather, I find no similarities in the purpose, application, and design of the claimed invention and the technology described in Rosenberg;
- 12. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.